

EPA 823-R-07-006

**REPORT OF THE EXPERTS SCIENTIFIC WORKSHOP ON CRITICAL
RESEARCH NEEDS FOR THE DEVELOPMENT OF NEW OR REVISED
RECREATIONAL WATER QUALITY CRITERIA**

**Airlie Center
Warrenton, Virginia
March 26-30, 2007**

**U.S. Environmental Protection Agency
Office of Water
Office of Research and Development**

June 15, 2007

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**DRAFT
EXECUTIVE SUMMARY
BY WORKGROUP CHAIRS**

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**U.S. Environmental Protection Agency
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July 13, 2007

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ACKNOWLEDGMENTS

EPA would like to thank the experts and others who participated in the *Experts Scientific Workshop on Critical Research Needs for the Development of New or Revised Recreational Water Quality Criteria*. Their dedication and hard work at and following the workshop to produce the proceedings are greatly appreciated. EPA would also like to thank the workgroup chairs who worked collaboratively after the workshop to produce this Executive Summary.

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EXECUTIVE SUMMARY

The *Experts Scientific Workshop on Critical Research and Science Needs for the Development of New or Revised Recreational Water Quality Criteria* took place at the Airlie Center in Warrenton, Virginia, from March 26 to March 30, 2007. Forty-three U.S. and international experts from academia, numerous states, public interest groups, U.S. Environmental Protection Agency (EPA or the Agency), and other federal agencies, met to discuss the state of the science on recreational water quality research and implementation issues.

The purpose of the workshop was for EPA to obtain input from individual members of the broad scientific and technical community on the “critical path” research and related science needs for developing scientifically defensible new or revised Clean Water Act (CWA) Section 304(a) recreational ambient water quality criteria (AWQC) in the near-term. Near-term needs were defined as those specific research and science activities that could be accomplished over the next 2 to 3 years so that results would be available to EPA in time to support development of new or revised criteria. EPA would publish the new or revised criteria in roughly 5 years (2012).

Experts were assigned to one of seven workgroups to discuss the following seven topics essential for EPA’s development of new or revised criteria: (1) approaches to criteria development; (2) pathogens, pathogen indicators, and indicators of fecal contamination; (3) methods development, (4) comparing risks (to humans) from different sources; (5) “acceptable risk”; (6) modeling applications for criteria development and implementation; and (7) implementation realities. The workshop proceedings dedicate a chapter to each of these seven topics.

Drafts of the seven chapters of the report were written by the experts at the workshop. Subsequently, the chairs of the respective groups worked with EPA to finalize each chapter and prepare this Executive Summary. Because the workshop’s purpose was to obtain individual input from each expert, the report is necessarily a summary of individual views. Thus, commonalities and differences in expert opinion are acknowledged throughout the workshop proceeding. During their deliberations, experts were asked to consider the following four main applications and implementation issues associated with AWQC for recreational waters: (1) listing of impaired waters under CWA §303(d); (2) total maximum daily load (TMDL) calculations for impaired waters; (3) National Pollutant Discharge Elimination System (NPDES) permits; and (4) recreational water monitoring and notification.

Because of the diverse nature of watersheds throughout the United States, there was general agreement among experts that criteria that have flexibility are desirable. A common statement from a number of workshop participants was that a “one size fits all” criterion is inadequate for public health protection and the compliance applications under the CWA. Workshop participants agreed that EPA should develop implementation guidance, including monitoring protocols, concurrently with development of new or revised §304(a) AWQC, and that the criteria and implementation guidance should be released simultaneously. This would facilitate acceptance and adoption by States, Tribes, and Territories.

Various workshop participants suggested areas for EPA to improve lines of communication, including with state and local governments and the public, by means of clear implementation

guidance and timely risk communication and education activities. Experts also urged EPA to communicate with other researchers who are planning to conduct relevant studies in the near term; importantly, researchers who plan to conduct epidemiological studies of swimmers and adverse health outcomes during the summers of 2007 and 2008 to determine if any of the methods being used are appropriate for inclusion in EPA's planned summer 2007 studies. Whether a particular method or tool (e.g., indicator type, quantification assay, use of watershed and/or predictive models) is appropriate for addition to EPA's planned epidemiological studies could be judged based on whether that indicator or method is important for one or more of the four high priority research paths discussed below.

Summary of Critical Path Research

The workshop participants identified the following critical path research areas as high priority: (1) human health impacts from different sources of fecal contamination; (2) measurement issues: climatic, geographic, and temporal variability; (3) determining risk level and subpopulations of concern; and (4) indicators and methods for measuring fecal contamination.

Human Health Impacts from Different Sources of Fecal Contamination

There was broad support among the workshop participants for conducting research and including in the new or revised criteria provisions that account for differences in risks associated with human versus nonhuman sources of fecal contamination, and point versus non-point sources—regardless of the framework ultimately proposed for the criteria. The absolute risk levels and the magnitude of differences between animal and human waste associated risks are not well characterized and may vary greatly geographically and temporally. Point sources and non-point sources of fecal contamination also differ in risk and those differences are not well characterized. Workshop participants suggested enhancements to epidemiological studies, quantitative microbial risk assessment (QMRA), development of quantitative sanitary investigations, and models to aid in sanitary investigations to help characterize risks.

Epidemiological studies are the preferred approach to define and quantify human health risks from exposure to pathogens in recreational waters. Two principal study designs have been used in previous studies of recreational waters—randomized control trials and prospective observational cohort studies. Epidemiological studies have historically been used to assess human health risks at beaches impacted by point sources of fecal contamination. However, the need for additional epidemiological studies, especially at non-point source impacted beaches, is viewed as essential to better define risk and guide future criteria development. In future epidemiological studies, consideration should be given to enhanced study designs as well as use of both study designs simultaneously.

QMRA can be used to rank the relative risks of different exposure scenarios, such as recreational sites impacted by animal versus human fecal wastes, where no direct epidemiological information is available. QMRA can also supplement existing epidemiological data, such as has been done in a number of specific case studies in the United States and in other countries. QMRA has the ability to consider infectivity of specific pathogens from a variety of fecal sources and their fate and transport in waterbodies to estimate risk.

Quantitative sanitary investigations for watershed characterization could be used to classify water quality based on relative risk, with waters that are more likely to be impacted by human waste being assigned a higher risk. Some methods for watershed characterization include the following: methods for sanitary investigations, methods for fecal source identification, and modeling to determine which watershed characteristics are related to risk of illness. Quantitative sanitary investigations can address multiple concerns regarding the applicability of criteria, including the impact of different sources of fecal contamination. The details of how quantitative sanitary investigations can be designed and implemented on a national level have yet to be determined and were not substantively addressed by the workshop participants; in part because the process by which the details would be determined is likely to be lengthy and iterative, though the details will be important for implementation.

Related Key Near-term Science and Research Needs:

[bracketed numbers correspond to the report chapters in EPA 823-R-07-006]:

- Develop methods to quantify the difference in risk to human health from human versus animal fecal material in recreational waters. [1, 4, 7]
 - Conduct epidemiological studies at locations influenced by different types of animals but that are not influenced by treated sewage (wastewater) effluent or other human fecal sources. [2]
 - Identify data gaps and collect data that are important for conducting QMRA studies for estimating health risks from different sources of fecal contamination (e.g., humans, domesticated animals, birds, point, non-point), particularly when epidemiological data are not available. [4]
 - Conduct QMRA studies to estimate the risk of low probability/high impact illnesses from human exposure to animal waste in recreational waters. (Animals can harbor many bacterial and protozoan pathogens that pose a human health hazard and some of these pathogens, such as enterohemorrhagic *E. coli*, can cause serious, life-threatening illness in humans.) [4, 5]
- Determine potential exposure levels and the associated health risks to intermittent microbial pollution discharges, combined sewer overflows (CSOs), urban runoff, and concentrated animal feeding operations (CAFOs). One aspect of exposure includes whether swimmers are likely to be in the water during these events, and if so, collect appropriate data (e.g., for complementary QMRA studies). [7]
- Develop protocols for using simple, heuristic, statistical models that correlate watershed activities (presence of sewage treatment plant effluents, agricultural activities, domesticated animals) and attributes (slope, soil type, climate, soil moisture) to the susceptibility of a waterbody to exceed new or revised criteria levels. [6]
- Develop quantitative rather than qualitative sanitary investigation tools. A tiered assessment of the watershed, starting with traditional fecal indicators (conservative measures) and progressing to select a suite of indicators that provide source specificity and load information, was suggested as one possible approach. [1, 2, 7]

- Develop indicators and associated methods for differentiating between human and animal fecal contamination. These methods could be part of a second or third tier of steps in evaluating a watershed, regardless of what criteria approach is selected. [2, 3]

Measurement Issues: Climatic, Geographic, and Temporal Variability

There was broad support among the workshop participants for conducting research and including in the new or revised criteria provisions that account for differences in climatic regions and geographic areas. Workshop participants were in agreement that the current state of the science calls for the new or revised criteria to be based on indicators of fecal contamination. Experts also agreed that enterococci and *E. coli* are probably not appropriate indicators in all climatic regions (e.g., in tropical and subtropical climates) and geographic areas. Appropriate indicators that correlate with recreator illness rates in tropical and subtropical climates are needed. New or revised criteria need to be applicable in areas where currently accepted indicators of fecal contamination, such as enterococci, may not be strongly correlated with observed excess illness rates. The workshop participants felt that there is no scientific rationale to support different risk level targets between geographic areas (i.e., freshwater and marine water) or between climatic regions (tropical, subtropical, temperate).

Workshop participants agreed that the spatial and temporal variability evident in indicator data sets, as well as the delay in obtaining monitoring results using conventional culture-based methods, rendered the single sample standard impractical for routine water quality notification purposes. Simple statistical models that do not necessarily require an understanding of processes and mechanisms have the potential to be incorporated into the new criteria, particularly for beach monitoring and water quality notification purposes. These models relate water quality to environmental factors like wind speed, prior rainfall, and tide level. Models have been demonstrated to serve as valuable tools for making closure or advisory decisions while managers wait for laboratory results, thereby providing for improved public health protection for swimmers as compared to relying on bacterial indicator monitoring alone. Also, once a model is site-validated with a sufficient baseline of monitoring, further monitoring could be reduced and targeted to instances where the model predicts exceedences of the criteria. The Modeling workgroup members felt that due to time-lag notification errors and temporal variation known to exist in indicator data series, day-to-day water quality notifications should not be issued using a single sample standard in conjunction with a microbial assay that takes longer than a few hours.

Related Key Near-term Science and Research Needs:

- Identify and develop indicators and corresponding methods that are appropriate for use in tropical and subtropical recreational waters. Conduct epidemiological studies to link those indicators with illness at tropical and subtropical locations. [1, 2, 4, 5]
- Increase the diversity of climatic regions and geographic areas where epidemiological studies are conducted. Also include different types of recreational waters, such as flowing (inland) waters. [3, 7]

- Gain better understanding of temporal and spatial variability in environmental sampling using culture-based and non culture-based methods and the implications for their use in representing water quality. [2, 4]
- Conduct research to better understand the human health significance of regrowth and persistence of indicator bacteria in nutrient enriched surface waters and sand/sediments and how those impact water quality determinations. [5]
- Ensure that QMRA studies conducted for estimating health risks from swimming in recreational waters include parameters and assumptions that are applicable for temperate, subtropical, and tropical climates. [4, 5]
- Determine if data are sufficient to conduct QMRA studies for evaluating health risks from flowing waters and collect data if possible and necessary. [7]
- Develop, test, and validate water quality models for different water types with a wide range of fecal sources and locations to improve notification accuracy. [6]

Determining Risk Level and Subpopulations of Concern

Workshop participants felt that (1) risks to children should be considered as the basis for determining risk level associated with new or revised criteria, and (2) timely risk communication and education of the public are critical for future acceptance of new or revised criteria. Social sciences research is needed to inform risk communication strategies and to examine what the public considers to be an “acceptable” level of risk for swimming-related illnesses. However, the Acceptable Risk workgroup members agreed that the term “acceptable risk” is flawed and should be avoided during the process of developing new or revised recreational AWQC.

Workshop participants felt that the risks to children should be better characterized and that a better understanding of risks to children may help inform policy decisions regarding selection of the risk level that will be associated with new or revised criteria. Epidemiological data indicate that children can have a higher risk of illness than adults from swimming in fecal contaminated recreational waters. Two factors contributing to this difference are (1) increased exposure from ingestion of higher volumes of water, and (2) greater susceptibility due to immunological differences compared to healthy adults. Note, workshop participants agreed that criteria should not be established based on the susceptibility of immunocompromised individuals; rather, targeted risk communication and public health messages could be used to advise these individuals that they are at increased risk of illness and are advised not to swim.

Workshop participants emphasized that clear and transparent communication with all stakeholders is important for the process of developing and implementing new or revised criteria. A tiered communication plan may be an effective approach for better informing the public about the criteria and how to interpret beach advisories and closings. Depending on the individual’s level of interest or need, the information could be basic (e.g., a sign at a beach) or more detailed (e.g., pamphlets, websites). Workshop participants felt that EPA has a role in assisting State and local officials in developing risk communication strategies.

Related Key Near-term Science and Research Needs:

- Review existing recreational water-related epidemiological studies to evaluate risks to children. [1, 5]
- Include the ability to evaluate specific risks to children when developing new epidemiological studies. [1, 4, 5]
- Include some element of assessing acceptability of risk in the upcoming epidemiological studies, such as adding a sociological component. [5]
- Initiate studies to assess how impacted groups understand and perceive risks associated with recreational water use and what level of voluntary risk would be acceptable. [5]

Indicators and Methods for Measuring Fecal Contamination

Workshop participants felt that new or revised recreational AWQC should be based on fecal indicators. The level of occurrence and the types of pathogens in ambient waters vary greatly both temporally and spatially. Some pathogens are only present in very small concentrations, yet may present a public health risk. Because of these factors, methods to detect and quantify specific pathogens in ambient waters are not sufficiently developed at present to be practical for use in the near-term timeframe. Therefore, using suites of pathogens as the basis for new or revised criteria was not favored among workshop participants as a first “line of defense.” However, pathogen monitoring may be useful as a subsequent tier for microbial water quality evaluation. For longer term research needs, further development of pathogen detection methods may result in a more important role.

There was broad expert support for new and/or improved methods for enumeration of fecal contamination and specific pathogens; however, methods need to be evaluated in the context of how they are going to be used for specific CWA applications. The workshop participants felt that rapid methods are needed in some but not all water quality management situations.

Future epidemiological study design efforts should integrate sanitary investigation and water quality modeling and incorporate characterization of the source of fecal contamination, including measurement of pathogens and indicators. The latter includes identifying the etiological agents in the source of fecal contamination and that cause illness in the subjects enrolled in the epidemiological studies.

Many of the enhancements of methods and tools discussed throughout these proceedings are likely to take longer than 2 to 3 years. Therefore, the further development of these methods and tools should be proactively pursued to facilitate future enhancements (beyond 2012). In situations where method and tool development proceed rapidly, then those methods and tools would become candidates for integration into new or revised criteria in the next 5 years.

Related Science and Research Needs:

- Evaluate and validate performance characteristics of methods that are linked to new or revised criteria and ensure that those methods are developed into official EPA Methods. [1, 2, 3]

- Develop and demonstrate the robustness of new methods for existing indicators (e.g., new ways of quantifying enterococci). [3]
- Develop new methods for new indicators, including but not limited to *Clostridium perfringens*, adenoviruses, coliphages, and *Bacteroides*, to either replace or augment the current bacterial indicators. [3, 4]
- Develop methods for enumeration of pathogens and indicators in wastewater. [1, 3]
- Develop methods for source identification to support watershed characterization activities. [3]
- Develop methods related to specific pathogens and fecal source identification for use in a second tier of tests to provide for a more refined assessment of risk of human illness. [1,3]
- Conduct fate and transport studies to determine relationships between current and new fecal indicators, index pathogens, and priority pathogens in treated effluents and in recreational water to better inform the applicability of those indicators and pathogens for specific CWA criteria uses. [2, 4, 7]

Summary

EPA would like to thank the workgroup chairs and other experts for their valuable contributions to the workshop deliberations, proceedings, and this Executive Summary, and on the state of the science of recreational water quality research and implementation issues. EPA intends to use these reports as it develops a critical path science plan that will help guide Agency research activities over the next 2 to 3 years in support of the development of new or revised recreational AWQC. These research activities could be a combination of Agency-sponsored studies, collaborative arrangements with external investigators and groups, or coordination of projects with external investigators to help supplement Agency efforts.

CHAPTER 4

COMPARING RISK (TO HUMANS) FROM DIFFERENT SOURCES

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4.1 Introduction

Fresh and marine recreational waters and beaches may be impacted by human and/or animal feces from point and non-point sources. Studies have recently been completed by EPA on assessing rapid water quality indicators and their ability to predict swimming-associated illness at freshwater beaches impacted by publicly (and privately) owned (sewage/wastewater) treatment works (POTW) systems. Similar EPA studies are currently planned (starting summer of 2007) to assess the risk of illness for people who swim in marine recreational waters impacted by POTW systems (point sources of fecal contamination). Thus, in the near future additional information should be available on risk of illness for bathers at marine beaches largely impacted by human sewage. Plans are also underway by the Southern California Coastal Water Research Project to assess swimming risks at least one marine beach that is impacted by non-point source sewage that likely contains a mixture of human and animal feces. However, there remains a paucity of data on the risk of illness for swimmers at beaches exclusively (or primarily) impacted by feces from animals. The absence of such data makes it difficult to interpret the health significance of the frequent and persistent elevated fecal indicator levels in such waters that have been attributed to animals in many locations throughout the United States.

It is widely believed that human feces pose a larger health risk than animal feces to swimmers and other primary contact recreational water users. This belief derives from the basic concept that virtually all enteric pathogens of humans are infectious to other humans, while relatively few of the enteric pathogens of animals are infectious to humans. Possible exceptions are bird flu virus and swine hepatitis E virus (HEV). Workgroup members regarded the evidence for swine HEV transmission by water to be very weak and felt that it could be disregarded in terms of risk assessments during the next 2 to 3 year EPA planning period. Bird flu was discounted as a major concern for swimmers because it was felt that if an outbreak of bird flu was recognized in birds or humans in the United States, early public health recommendations would include directives for people not to swim in waters that might be impacted by bird or human feces, including chlorinated public pools.

Counterbalancing the concept that animal feces may pose a lower risk is recognition that animals do harbor many bacterial and protozoan pathogens that pose a human health hazard and that some of these pathogens, such as enterohemorrhagic *E. coli* (EHEC), can cause serious, potentially life-threatening illness in humans. In addition, animal feces are often directly deposited in freshwater that receives no treatment before reaching bathing areas. The concentration of both feces and pathogens may be sufficiently high at beach locations at various times to pose a significant health risk to swimmers.

The bottom line is that there are few data to demonstrate whether animal feces pose a lower, greater, or equivalent health risk to bathers than human feces. If there is a difference, it would be helpful to know the magnitude of that difference in order for EPA to make appropriate public health recommendations. The only way to get a better sense of the health risk for swimmers posed by animal feces is to conduct targeted studies. Some types of studies (epidemiological and quantitative microbial risk assessment [QMRA] studies) would produce quantitative estimates of risks while others (fate and transport, pathogen loads in water, etc.) would provide supporting information or stand alone qualitative information about risk.

It is recognized that there are many different types of animals and that the pathogen risks posed by feces from these animals are different. These differences, as well as the different pathways (point, non-point, fecal deposition on land versus in water, etc.) that feces reach bathing areas, have to be taken into account in weighing risk. Workgroup members approached the issue by developing Table 5 in order to rank the likely risks from different sources of fecal contamination and to help prioritize which bather/animal-fecal-risk interface studies should be undertaken first.

The initial workgroup member discussion focused on assessing the universe of pathogen sources of interest to recreational waters. Workgroup members developed a table (Table 5) in which the major sources of fecal contamination categories are in rows. The major rows are wildlife, agricultural animals, domestic animals (pets), human/sewage, and what the workgroup termed “secondary environments” (i.e., soil, sand, and sediments). The wildlife row is subdivided into aquatic birds and all others. The agricultural animals are divided into poultry and other (largely comprised of domestic livestock such as cattle, sheep, and pigs). The human/sewage is divided

Table 5. Comparing Risks (to Humans) from Different Pathogen Sources.^a

Source	Viruses	Protozoa	Bacteria	
Wildlife				
Aquatic birds	N	L	L-M	
Other (e.g., deer)	N	M	M	#2 priority
Agricultural animals				
Poultry	N	N	M-H	
Other (e.g., cattle, sheep)	N	M	M-H	#1 priority
Domestic animals				
Pets (e.g., dogs, cats)	N	L	L	
Fecal shedding by bathers				#3 priority
Adults	L	L	L	
Children	H	H	H	
Sewage				
No treatment (combined sewer overflows)	H	H	H	
No treatment (separate storm sewer overflows)	?*	?*	?*	
Secondary treatment**	H	H	M	
Plus chlorine**	H	H	L	
	M-H (L with increased energy)			
Plus UV			L	
Secondary environments***	L	L	M	
^a Does not have an explicit fate and transport component * Risk largely depends on amount of human feces present ** Focus of most (U.S.) recreational water epidemiological studies *** Sediment suspension and contact with beach sand N = estimated no or negligible risk, L = estimated low risk, M = estimated medium risk, H = estimated high risk				

into untreated sewage, secondary treatment sewage, chlorinated sewage, and UV-treated sewage. Fecal shedding by bathers (adults and children) is considered separately.

The columns are defined by broad microorganism groups of viruses, protozoan and bacteria. By an expert opinion process (within the workgroup) each cell of the table was given a risk estimate of no (zero) or negligible risk (N), low, medium, and high (L, M, H). The types of characteristics discussed included infectious dose, numbers of pathogens per gram of stool from infected animals, implication of source in waterborne disease (extended discussion on foodborne disease and vector-borne disease), persistence and survival in the environment and finally an assumption that sources are in close proximity to a primary contact recreational area. The N, L, M, H risk designations in the table cells represent the workgroup's "best guesses" and assumed that animal feces was deposited in freshwater relatively closed to bathing sites. The workgroup did not specifically address pathogen "die-off" associated with fecal deposition on land (spring/summer temperatures resulting in pathogen drying, transport from soil to water affects on viability, etc.). It was felt that many of these types of data are available and that the table could be updated with real data at a later date as a separate project. It was recognized that updating the table with published data might change the values in one or more risk rankings of the table cells.

With rare exception, viruses are species-specific. Essentially, all enteric oral/fecally transmitted viruses that infect humans are of human origin. For all of the animal viral sources of pollution, the viral cells were given a zero or negligible risk (indicated by "N" entries in Table 5). All the human sources were given a high risk estimate with the exception of UV-treated sewage. UV-treated sewage at current levels has up to a 0.5-log reduction of viruses and hence this cell was assigned a medium risk. More energy intensive UV irradiation may provide up to a 4-log viral reduction and result in a low risk ranking. Sentinel viruses for this group include enteroviruses, hepatitis A virus, norovirus, rotovirus, and adenoviruses. The major protozoan pathogens of concern are *Giardia* and *Cryptosporidium*. Given the current knowledge of infectious dose, the long survival in the environment, many of the animal cells within the table were given a low, low-to-medium, or medium risk level. As with the viruses, all the human cells within the table were given a high risk rating with the exception of UV-treated sewage. The bacteria had similar ratings to the protozoa ranging from low-to-medium and again, the human sources were all assigned a high ranking with exception of chlorine- and UV-treated sewage that received a low risk ranking.

Bather density was divided into adults and children (recognizing that children could be divided into specific age groups) with the assumption that hygiene and accidental fecal discharges were much more likely to occur in children than adults. Thus, for adults, a low risk ranking was assigned across the columns and a high risk ranking was assigned for children.

Based on the few studies done on secondary environments, viruses and protozoa were given a low risk rating, while bacteria were given a medium rating.

In developing Table 5, workgroup members noted the following discussion points:

1. Current epidemiological literature suggests that the symptomatic profile of swimming-associated illnesses indicates primarily viral illnesses.
2. Certain pathogens such as EHEC have a low probability of occurrence but are associated with severe a health outcome.
3. Information available to the workgroup suggested that nonhuman fecal sources impacted freshwater sources more than marine water sources.
4. Combined sewer overflows (CSOs) were considered as untreated sewage.
5. Separate storm sewer overflows initially were put in the domestic animal row but subsequent discussion of recent studies suggested that they could have a human component in many communities.

In discussing the future research needs related to the development of new or revised recreational water quality criteria, the workgroup members defined the ultimate goal to be a determined quantitative risk estimate for each fecal source (row). The benchmark by which risks should be compared is the secondary and chlorine treated sewage row that is currently the focus of recently completed EPA National Epidemiological and Environmental Assessment of Recreational (NEEAR) epidemiological studies for freshwater and the planned marine water studies. The following research projects were suggested to meet that objective of determining a sound and defensible risk estimate for each row of Table 5.

4.2 Summary of Workgroup Discussions and Reflections on Workgroup-specific Charge and Questions

The charge to the workgroup was to consider the impact of waterborne pathogens from various sources, both human and nonhuman, on the health risk resulting from exposure to fecal contamination in recreational waters. Workgroup members considered the impact of the issue on beach monitoring and notification and the classification of waterways as impaired. The discussions were wide-ranging. Discussions began with the consideration of the relationship of likelihood of illness due to nonhuman sources to likelihood of illness predicted by the use of epidemiological data from human exposure to POTW-impacted waters using fecal indicators. Possible approaches to modifying the application of regulatory approach using considerations of infectivity to pathogens among species were debated. The location of fecal sources relative to the site of monitoring and the potential of animals to move off-site were also discussed. These topics are all reflected in the potential research activities proposed and discussed in this chapter.

Six charge questions were provided to the workgroup (see Appendix A) to help stimulate discussion, and to identify key issues for consideration. A brief synopsis of responses to the questions is presented below.

- *Question 1: Is setting criteria based on a treated human point source such as a POTW protective, under-protective or overprotective of other potential sources of human pathogen? Why or why not? Are there data to support this conclusion?*

Whether the criteria are protective would depend on the effectiveness of treatment in reducing the levels of pathogens and the relative reduction in indicator organisms. Secondary wastewater treatment with chlorination could provide a false sense of security for protozoa and viruses. This reflects the higher degree of effectiveness of chlorine in killing/deactivating bacteria relative to viruses and protozoa. Given that current indicators are bacteria and would be reduced to a greater extent than viruses and protozoa, low indicator levels might suggest that waters impacted by POTWs were relatively pathogen-free when they still contained a significant virus and protozoan load. Data are available to characterize the relative effectiveness of disinfection techniques across classes of waterborne pathogens and indicator organisms.

- *Question 2: Based on the “state of the science,” what conclusions or assumptions are reasonable to make about risks to humans exposed to human fecal contamination, non-point source contamination from animal sources, and mixed sources (e.g., combined sewer overflows [CSOs] and (separate) storm sewer overflows)?⁶*

Workgroup members felt that it is reasonable to assume that exposure to fecal contamination from untreated human waste posed the highest risk. Treated sewage was judged to be of lower concern, although it was more similar in risk to untreated human waste than to nonhuman sources. In general, treated and untreated sewage should be treated similarly for the purposes of evaluating risk. Discussion of CSOs led to the conclusion that they should be considered similarly to untreated sewage in terms of public health concern. Although separate storm sewer overflows were initially considered to be similar to animal waste in nature, there was a recollection of data in the literature (Haile et al., 1999) noting the occurrence of a significant occurrence of human pathogenic viruses in stormwater effluent and associated health effects merits further investigation. Aquatic avian sources were considered to be of low public health concern. Other wildlife and agricultural animal (including poultry) feces were deemed to be of moderate concern.

- *Question 3: To what extent is it reasonable to apply risk estimates from POTW-influenced beaches to non-POTW beaches? Do we understand scientifically whether this would lead to overprotection? What science would be important to understanding this?*

A portion of the answer to this question is reflected in the responses to Questions 1 and 2 above. The propensity to over- or under-protect would depend upon the source of the waste impacting the site. Non-point sources that largely reflect nonhuman sources of fecal contamination would probably be overprotected by studies in POTW-impacted locations. Mixed sources or untreated human sources may be inappropriately characterized by the POTW-dominated data. The workgroup’s generalizations are reflected in Table 5. Addressing the public health significance of CSOs and separate storm sewer overflows are problematic because of the site-specific nature of the extent to which they vary by site characteristics. Although the importance of dilution of pathogens and indicator organisms in runoff events was discussed, no conclusion was reached about its significance.

⁶ It is important to note that the workgroup was specifically charged (see Appendix A) to address (separate) storm sewer overflows and not sanitary sewer overflows, the latter of which are often discussed in conjunction with CSOs and commonly using the acronym “SSO.” For this reason, workgroup members decided to not use the acronym SSO anywhere in the chapter.

- *Question 4: Assess whether there is a possibility of overprotection due to a compounding of risks from multiple factors (such as the current definition of gastrointestinal [GI] illness [i.e., no fever]; more sensitive molecular-based methods; assuming that POTW risks = nonhuman fecal contamination source risks, etc.).*

This question was referred to the Acceptable Risk workgroup (see Chapter 5).

- *Question 5: How should EPA evaluate risk that may have a low probability of occurrence but a significant risk, if it occurs?*

This question was considered by workgroup members to be unlikely to be adequately represented by completed epidemiological studies due to the low incidence (or detection) of pathogens that are associated with severe health outcomes. However, this important public health issue might be addressed using quantitative microbial risk assessment (QMRA) methods or by using large-volume filtration in future epidemiological studies.

- *Question 6: What are the key data gaps and uncertainties needed to support criteria development in the near term?*

The research needs and their prioritization are presented in a separate section (4.4). Epidemiological studies were given a high priority, with QMRA as an important adjunct. Additional epidemiological studies were encouraged by workgroup members because the data produced directly measure outcomes of interest (e.g., GI illness) and the data produced are more directly comparable to data being obtained for human health risks at marine beaches largely impacted by human sewage. Thus, epidemiological studies were preferred to the extent that they were possible and were viewed as an anchor for QMRA studies. However, it was recognized that it may be difficult to find freshwater recreational sites with sufficient bather activity to provide adequate sample sizes for an epidemiological study. If suitable sites cannot be found, then modeling the risk using QMRA techniques based on available epidemiological information would provide quantitative risk estimates that could help with short-term decision making on health risks. Similarly, if pathogen-source combinations in Table 5 cannot be conducted, it may be possible to use QMRA to provide quantitative risk estimates.

4.3 Options for Approaches and Implementation Considerations

The considerations in the followings section are not applicable to the current U.S. approach (i.e., US EPA, 1986; see also Chapter 1) because there is no way to take into consideration the charge to this workgroup on comparing risk to humans of fecal contamination from different sources. The following considerations are applicable to both the European Union (EP/CEU, 2006) and WHO (2003) approaches to criteria development. The sanitary investigations are important for the topics discussed by this workgroup. Simultaneous use of multiple indicator organisms or a tiered approach may be necessary.

4.4 Research Needs

1. Prioritize the next generation of studies. The purpose of these studies is to (1) revisit the ratings using a more thorough literature review and (2) gain as much information as currently exists on the magnitude of the fecal pathogen source problem across the United States.
 - a. Quantify the magnitude of difference in the risk of illness from different exposure sources (see Table 5) to see if they are different from POTW-impacted waters.
 - i. Initial estimate of risk – populate the table with infectious dose data and likely number of organisms excreted in stool per gram to characterize fecal source rank.
 - ii. Magnitude across the United States
 1. Number of impaired waters
 2. Number of beaches affected by the sources (number of affected bathers if available)
 - iii. Identify potential fresh and marine recreational sites for each of the fecal pathogen sources (rows) for future epidemiological studies. Priority should be given to freshwater sites.
2. Identify and characterize potential sites for future epidemiological studies using the following sources of information:
 - a. National Pollution Discharge Elimination System (NPDES) – provides location of all point source dischargers and their levels of discharge
 - b. CWA §303(d) list and §305(b) reports
 - c. Sanitary investigations and microbial source tracking to confirm site characterization
 - d. Compile information (via literature review and/or site-specific) about pathogen loads in non-point source water impacted by all sources of fecal contamination (human and animal), characterizing with respect to pathogens and indicators in freshwater versus marine water.

4.4.1 Epidemiological Studies

Workgroup members agreed that epidemiological studies are the most desirable approach to define and quantify health risks to humans swimming in fecally contaminated waters. Although many epidemiological studies have been previously conducted at point source-impacted beaches, very few such studies have been published on non-point source-impacted recreational waters. The relationship between current water quality indicators and health outcomes that is currently used in regulating beaches was developed from studies at point source-impacted beaches where water quality indicator levels correlated with swimming-associated illness (US EPA, 1986). It is plausible that the relationship between water quality indicators and health is different at non-point source-impacted sites since indicator levels may be high due to animal (e.g., birds, other wildlife) or other sources that do not increase the risk of human illness. Some workgroup members felt that it is appropriate to conduct epidemiological studies at non-point source-impacted sites to better define risk and guide future regulations.

Some workgroup members noted that epidemiological studies cannot be performed in all of the various types of non-point source-impacted waters for which there is a need to know risk. In many of these types of sites, other techniques (such as QMRA) will necessarily have to be used (see Section 4.4.2). The choice of the specific sites (beaches, rivers, lakes) in which to conduct epidemiological studies could be guided by the risk rankings developed in Table 5. These rankings include the types and concentrations of pathogens present, the number of affected waters across the United States, the number of people who are exposed to such sites, and the number of sites affected by regulatory restrictions under the CWA §303(d) guidelines.

Two principal study designs have been used in prior beach epidemiological studies—the randomized controlled trial (RCT) and the prospective observational cohort. The RCT has been primarily used in European studies and the observational cohort in many countries. Workshop participants discussed the relative strengths and limitations of each study design. With respect to the issue of health risks in non-point source-impacted waters, the workgroup members actively discussed the advantages of each design and felt that each had merit. Because of the required sample size (i.e., number of swimmers) is much less for an RCT, workgroup members could envision situations in which an RCT could be employed in future non-point source epidemiological studies. Workgroup members did note that in the United States it would be more likely for such an epidemiological study to receive human subjects approval if the enrollment scheme were altered from the RCT that has been used in several European studies. In Europe, subjects are typically recruited and enrolled in the studies at sites distant from the beach and then brought to the study sites. Workgroup members discussed an alternate design for consideration in the United States; specifically, enrolling willing persons who are about to enter the water and randomizing them to either swim or not swim that day. As in all epidemiological studies, aggressive exposure measurements of the water ingested and measures of water quality (e.g., indicators of fecal pollution) to which the swimmer is exposed would be critical. In non-point source sites where adequate numbers of swimmers could be enrolled, the prospective cohort design could be used for epidemiological studies. Workgroup members felt that it would be very helpful at some point to use both study designs simultaneously on one beach. This would allow for a direct comparison of the results and help guide future epidemiological studies.

1. Epidemiological studies (**highest priority is to conduct studies at beaches impacted by different types of non-point sources of fecal contamination [see Table 5]**)
 - a. Randomized control trials (for consideration at beaches with low numbers of bathers)
 - i. European design should be modified for use in the United States (suggestion – randomize people about to swim into groups that will swim or not swim)
 - ii. Potential problem – identifying appropriate numbers of participants may be more difficult for inland (predominantly fresh) recreational waters than marine waters
 - iii. Estimated necessary sample size – 1,500 people/site
 - b. Prospective observational cohort study
 - i. Potential problem – identifying sufficient numbers of participants may be more difficult for inland recreational waters than marine waters

- ii. Estimated necessary sample size – 5,000 to 10,000 people/site (200 to 400 people/day)
- iii. Wide range of exposures needed

4.4.2 Quantitative Microbial Risk Assessment

Several workgroup members advocated for QMRA studies in developing new or revised recreational ambient water quality criteria (AWQC). In part because QMRA can be used to rank the relative risks of different situations, such as sites impacted by animal versus human fecal wastes, and where no direct epidemiological information is available. QMRA studies can also be instructive in recreational areas where such studies have already been completed.

QMRA is increasingly used to characterize risk to humans from exposure to contaminated water when engaging in “contact recreation,” especially swimming, but also other forms of water contact such as water skiing. It translates the environmental occurrence of pathogens and the volume of water that individuals are exposed to into a probability of infection or illness. Inputs with known variability are described by statistical distributions from which many random samples are taken, often using a “Monte Carlo” calculation procedure, to derive a risk profile.⁷

The following four step process is used: (1) identifying the important pathogens (“hazards”); (2) determining human exposures to contaminated water, via ingestion or inhalation; (3) characterizing dose-response, using data available from clinical trials, illness surveillance, and outbreak data; and (4) mathematically characterizing the risks and communicating risks and attendant uncertainties.

For step 1, a suite of sentinel pathogenic microorganisms should be considered for each situation as they are considered to cover the range of illnesses that could arise in the United States, such as the following:

- viruses – norovirus, Hepatitis A virus, caliciviruses, enteroviruses, rotavirus, adenoviruses;
- bacteria – EHEC, *Campylobacter* spp., *Salmonella* spp., *Shigella* spp.; and
- protozoa – *Giardia* cysts, *Cryptosporidium* oocysts.

The setting for each site of interest will dictate which of these pathogens should be used. For example, a recreational site impacted only by animal wastes should not need to include viruses. Adenoviruses will need to be included where aerosols may be inhaled (e.g., by water skiers).

For step 2, information on water ingestion and exposure rates, along with duration of the recreational activity, are combined with the concentration of pathogens in the water to obtain a

⁷ EPA’s Office of Water has developed a “complete draft” of a Protocol for Microbial Risk Assessment based on the EPA-ILSI (ILSI, 2000) *Revised Framework for Microbial Risk Assessment* (<http://www.ilsa.org/file/mrabook.pdf>) and which is consistent with the chemical risk assessment paradigm. The Agency has initiated a review to insure it meets risk assessment needs for all water-based media. Contact Stephen Schaub, EPA Office of Water (see Appendix B), for information on the Protocol for Microbial Risk Assessment.

dose—all these variables being described by statistical distributions. Information on the origin, quantity, and fate and transport of wastes deposited on a land surface and into waterways is of prime importance in determining the distributions of pathogens in the water that is subsequently ingested or inhaled.

For step 3, several dose-response analyses have been reported and may be used, albeit with caution. In particular, the form of the “dose” used in a clinical trial needs to be made consistent with the form used to describe the dose ingested or inhaled.⁸ Also, uncertainty in the dose-response equation, in the form of credible intervals, can be captured by the calculation process.

In step 4, risk profiles may be derived, in the form of a cumulative distribution function—this will be particularly useful for examining the risks associated with rare but highly significant illness (e.g., EHEC). This also enables uncertainty measures to be calculated. Comparing relative risks for different sites should be done by comparing risk profiles, rather than by comparing single risk “numbers.”

1. QMRA provides a range of possible illnesses or risks, allows comparisons across all fecal pathogen sources (see Table 5), and number of illnesses by a modeling approach (**highest priority is to conduct assessments at beaches impacted by different types of non-point sources [see Table 5]**). There was discussion among workgroup members regarding the strengths and limitations of conducting QMRA versus epidemiological studies (see Eisenberg et al., 2006); QMRA:
 - a. Is a potential alternative, adjunct, or precursor to epidemiological studies
 - b. Can evaluate infection and illness
 - c. Could evaluate sentinel (index) pathogens such as:
 - i. Bacteria (EHEC, *Campylobacter*, *Salmonella*, *Shigella*)
 - ii. Protozoa (*Giardia*, *Cryptosporidium*)
 - iii. Viruses (norovirus, Hepatitis A, caliciviruses, enteroviruses, rotavirus, adenoviruses)
 - d. Can consider inhalation as an additional route of exposure if data are available
 - iv. Adenoviruses
2. QMRA is a good way to compile information (via literature review and/or site-specific) about pathogen loads in source waters impacted only by animal sources (with an emphasis on freshwater) and to characterize pathogens and indicators.

4.4.3 Etiologic Agents

Workgroup members felt it important to emphasize that there is a glaring lack of knowledge about the incidence with which specific pathogens cause swimmer-associated illnesses at both non-point source- and point source-impacted beaches. Identification of such pathogens as the actual cause of illness in swimmers would provide important information for developing new or

⁸ For example, a rotavirus clinical trial will report dose as FFU (focus forming units); there may be many virus particles for each FFU.

revised recreational AWQC (or State Water Quality Standards) to enhance the protection of public health. In order to go forward with currently available technologies, the diagnosis of viruses could be made by exclusion of bacterial and protozoan pathogens causes of illness. Additionally, such information would be essential inputs into QMRA models to be used at recreational sites (or types of sites) where epidemiological studies cannot be conducted due to expense or insufficient numbers of swimmers. Because advances in modern techniques in microbiology now make a more complete identification of specific pathogens possible, workgroup members felt that the epidemiological studies currently underway and planned provide a unique opportunity to collect specimens (stool, saliva, and/or blood) from swimmers (and non-swimmers as controls) with which to identify the responsible waterborne pathogens. Such data would be complementary to the data collected in studies of pathogen occurrence in water that are presented elsewhere in this chapter and these proceedings. Workgroup members suggested that both types of pathogen occurrence information (in humans, in water) be collected during future epidemiological studies in order to minimize cost and maximize the utility of the information.

1. Identify etiologic agents of swimming-associated illness.
2. Pilot approaches for identifying etiologic agents in planned and ongoing epidemiological studies.
3. Classify etiologic agents in ill swimmers by broad groupings (i.e., viral, bacterial, protozoan).
4. Develop and evaluate sample collection techniques (stool, salivary antibodies, blood).

All of the above could be done as an adjunct to epidemiological studies.

4.4.4 Fate and Transport

Because direct pathogen detection is not feasible on an ongoing basis, a surrogate measure relating water quality conditions to human health risk is required. When developing the appropriate indicator(s) to use in this approach, knowledge of the fate and transport characteristics of the pathogens and indicator(s), both individually and as they relate to each other is critical.

Individually, fate and transport is significant because only those pathogens that are present and viable in a given waterbody pose a potential public health risk. These pathogens are typically divided into the following three major categories: viruses, bacteria, and protozoa. Because the microbiological characteristics of each of these groups are significantly different, it is not unreasonable to assume that their fate and transport characteristics will vary (perhaps significantly) as well.

The most simplistic route of pathogen transport is direct deposition. Once the pathogen(s) (assumed to be carried in the feces of warm blooded mammals) is excreted over or in the water, the question is twofold—how long will the pathogen be viable and available (i.e., persist in the water column).

Indirect deposition of feces introduces a more complex situation. First, the fecal properties of different mammals can vary substantially. One of the primary differences (aside from pathogen and indicator density) is moisture content. That is, very “wet” feces is more likely than “dry” feces to introduce pathogens into the aquatic environment. After defecation, the distance of the feces from surface water plays an important role as well. Driven by precipitation and transported primarily via surface runoff, the pathogens are typically washed into the surface water either by sheet flow or are collected and discharged through a storm water collection system. During this transport, they are subjected to a variety of environmental factors—including, but not limited to, UV disinfection, predation, temperature—that affect the proportion that will ultimately end up in surface water in which people are recreating.

Another category of indirect deposition includes point source discharges, such as POTWs, CSOs, concentrated animal feeding operations (CAFOs), and other NPDES permittees. In addition to the issues identified above, the effect of the treatment processes that these effluents are subjected to plays a role in fate and transport of the pathogens.

Resuspension from sand, soil, or sediment (i.e., secondary environments) can also play an important role in pathogen fate and transport. There may be a reservoir of indicator(s) and/or pathogens that could be reintroduced into the water column. Additionally, regrowth of either the indicator(s) or pathogens could represent a source and/or confound the risk assessment/prediction.

Ideally, the indicator(s) chosen as the surrogate for the pathogens will have the same fate and transport characteristics of the pathogens themselves. However, since this is unlikely, it is important to know and relate the characteristics that are specific to the indicator(s) and the pathogens so that the measurement of the indicator can be correlated to the concentration of the viable pathogens in the water and ultimately to public health risk.

A number of studies have been published on the fate and transport of many waterborne pathogens and current indicator organisms. Therefore, a literature review to identify any data gaps so that additional studies may be designed and also to inform QMRA studies would also be useful.

1. Conduct fate and transport studies for indicators and sentinel (index) pathogens.
2. Conduct literature review to identify data gaps and to inform QMRA.
3. Identify indicators that have the similar fate and transport characteristics as pathogens.
4. Should include assessment of risk of pathogens and indicators being resuspended from sand, soil, and sediments (secondary environments).

4.4.5 Determine the Occurrence of Pathogens in Impacted Recreational Waters

The pathogen occurrence and pathogen concentrations in water impaired by animal feces in one or more non-point study site(s) (e.g., beach impacted by [non-CAFO] agricultural animal runoff; Table 5, priority #1) could be compared with pathogen load in planned POTW-impacted marine epidemiological studies. It is also proposed that investigators consider using high-volume, tangential-flow water filtration methods that were recently developed for assessing bioterrorism

threats to drinking water. This technology was designed to simultaneously capture very low concentrations of viruses, bacteria, and parasites in 10 to 100 L of water using a single collection apparatus (filter and pump). Although the equipment and pathogen recovery methods were initially designed to work on finished drinking water, there has been additional research to adapt the process for use on raw water supplies. The raw water application of this technology may be sufficiently understood for its employment in current or planned studies within the next 2 to 3 years. If the methods have not yet been adequately evaluated for this purpose, EPA may wish to encourage fast tracking their development for use in recreational water epidemiological and related field studies. Use of the large volume filtration tools might also be helpful to assess risks associated with low probability events that have serious health consequences (e.g., EHEC).

1. Determine the occurrence of pathogens in affected waters using the high volume filtration currently being developed for counter bioterrorism purposes.

4.4.6 Bather Studies

Bathers themselves can be a source of both indicator organism and pathogens in recreational waters (Elmir et al., 2007). Workgroup members suggested the following studies to determine the magnitude of this problem and/or the conditions at recreational sites in which this would be a problem.

1. Conduct additional studies on the impact of bathers on levels of indicator organisms and as a source of infectious pathogens for other bathers.
2. Develop better tools for assessing bather density.
3. Incorporate bather density into the study design and analysis of future recreational water epidemiological studies.
4. Conduct additional studies on human shedding in a controlled setting with a focus on young children.
5. Incorporate bather contribution to indicators and pathogens in QMRA studies.

4.4.7 Additional Research (Either Short- or Long-term Depending on EPA Priority-setting)

The following research would also enhance many of the ongoing and future efforts described in this chapter and elsewhere in these proceedings.

1. Include epidemiological data in predictive modeling efforts. This would broaden the use of both epidemiologic and modeling data. Many recreational epidemiological studies collect an extensive set of environmental data. Whether this is sufficient to accomplish environmental modeling is unknown. Both modelers and epidemiologists should discuss the feasibility of this effort.
2. Develop a method for accurate exposure assessment among swimmers. Exposure assessment in terms of water contact and quantity of water swallowed or inhaled is an area of potential misclassification in observational epidemiologic studies. The following would improve exposure assessment in epidemiologic studies:

- a. Develop individual sampling devices.
- b. Develop methods and conduct studies to determine the quantity of water ingested and inhaled in recreational settings. Consider studying secondary recreational contact for potential comparison.

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